



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

June 16, 2010

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 5813-40,
Clorox Disinfecting Bathroom Cleaner

From: Emily Mitchell, Branch Chief *Em*
Product Science Branch
Antimicrobials Division (7510P)

To: Velma Noble, PM 31
Regulatory Branch I
Antimicrobials Division (7510P)

Producer: The Clorox Company
7200 Johnson Drive
Pleasanton, CA 94588-8004

Formulation from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
n-Alkyl (C ₁₄ 60%; C ₁₆ 30%; C ₁₂ 5%; C ₁₈ 5%)	
dimethyl benzyl ammonium chloride	0.1375%
n-Alkyl (C ₁₂ 68%; C ₁₄ 32%)	
dimethyl ethylbenzyl ammonium chloride . . .	0.1375%
<u>Other Ingredients</u>	<u>99.7250%</u>
Total	100.0000%

I BACKGROUND

The submitted sample, was tested by the Michigan Department of Agriculture as a part of the Antimicrobial Testing Program. On November 25, 2009, the laboratory received 4 (1 quart) bottles of the product. Sample number 09ANAN000015 (Lot Number A49044GA1) was used to evaluate hospital disinfectant claims. The A.O.A.C. Germicidal Spray Products as Disinfectants Test Method was used to determine the effectiveness of the product against *Staphylococcus aureus* ATCC 6538 and *Pseudomonas aeruginosa* ATCC 15542 ready to use without an organic soil load and a contact time of 10 minutes at room temperature.

II USE DIRECTIONS

To Clean and Deodorize: Rotate nozzle to **FOAM** or to **SPRAY**. Spray 6-8 inches from the surface and allow product to penetrate dirt and soap scum. Wipe with a wet sponge or cloth and rinse with water. No scrubbing required. For tougher jobs, use **FOAM** option. Spray and let product stand for several minutes before wiping. For best results, use regularly to prevent soap scum buildup.

To Disinfect: Thoroughly clean the surface to be disinfected by following the above directions (remove excess dirt first in heavily soiled areas); reapply spraying entire surface until completely wet. Let stand 10 minutes before wiping. Use on the following hard, nonporous bathroom surfaces: glazed ceramic tile, shower doors, outside of toilet, plastic, chrome, fiberglass, glazed porcelain and synthetic marble. Do not use on natural marble, brass or varnished wood. Spot test all other surfaces in an inconspicuous area.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Products which are intended for use as broad-spectrum disinfectants labeled for use in hospitals, clinics, dental offices, nursing homes, and any other related institutions must meet the following testing requirements:

(1) **Test standard:** For initial registration, sixty carriers for each of three samples which represent three separate lots, one of which must be at least 60 days old, must be tested against each of the following *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). For the purpose of enforcement testing, only one product lot, instead of the three lots required for initial registration is tested.

(2) **Performance standard:** The product must kill all the test microorganisms on 50 out of each set of 60 carriers/slides to demonstrate effectiveness of the product as a disinfectant.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

The test method used in this assay was the required method by EPA Guidelines: A.O.A.C. Germicidal Spray Products as Disinfectants Test Method (Reference: Official Methods of Analysis, 2009, (961.02), Gaithersburg, MD. The product was tested undiluted. Testing for *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442) was initiated on March 23, 2010. All parameters for testing both organisms were the same. The carriers were exposed to the product for a contact time of 10 minutes at room temperature. D/E broth was used as the neutralizer broth and as the subculture media. Primary and secondary subculture tubes were incubated at 36+/-1°C for 48+/-2 hours.

V RESULTS

Sample Number	Lot Number	Organism	Carrier Count	No. Positive per Number Tested
09ANAN000015	A49044GA1	<i>Staphylococcus aureus</i>	2.1 x 10 ⁶ CFU	20/60
09ANAN000015	A49044GA1	<i>Pseudomonas aeruginosa</i>	1.0 x 10 ⁶ CFU	0/60

VI CONCLUSIONS

The submitted data does not support the effectiveness of the product, Clorox Disinfecting Bathroom Cleaner, EPA Reg. No. 5813-40, as a broad-spectrum or hospital disinfectant, tested against *Staphylococcus aureus* (ATCC 6538) when use undiluted without an organic soil load, and a contact period of 10 minutes at room temperature.

VII RECOMMENDATIONS

Since this product failed to demonstrate effectiveness against *Staphylococcus aureus* (ATCC 6538), it no longer qualifies for a label claim as a broad-spectrum or hospital disinfectant. The registrant for this product may use one of the following options to resolve this failure:

1. Remove the label claim for effectiveness against *Staphylococcus aureus* (ATCC 6538). The product no longer qualifies as a broad-spectrum or hospital disinfectant. All references to use in healthcare facilities must be removed from the label.
2. Retest the product against *Staphylococcus aureus* (ATCC 6538) to retain the label claim for effectiveness as a broad-spectrum or hospital disinfectant. This testing must be conducted on three batches of product, one of which is at least 60 days old, with 60 carriers per batch, using the A.O.A.C. Germicidal

Spray Products as Disinfectants Test Method, under the same conditions as those on the primary label.

- 3. If the registrant chooses to retest the product, they must contact Ben Chambliss on (703) 308-8174 to arrange for a split sample of the product to be delivered to the Agency for testing.**
- 4. Information regarding the results from this testing will be posted to the Agency's website.**

END